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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,695	03/06/2002	Joseph J. Florio	A02P1020US01	2497

7590

07/12/2004

PACESETTER, INC.
15900 Valley View Court
Sylmar, CA 91392-9221

EXAMINER

MANUEL, GEORGE C

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 07/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/092,695

Applicant(s)

FLORIO ET AL.

Examiner

George Manuel

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1, 15 and 16 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Schwartz '507.

Schwartz discloses a pulse generator 60 and vagal nerve stimulating leads 68 and 70 and teaches on detecting the onset of an arrhythmia amenable to control by stimulation of the vagal nerves, leads 68 and 70 provide such stimulation.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to

Art Unit: 3762

be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507.

Schwartz shows all of the claimed features except for a telemetry device for inputting signals.

One of ordinary skill in the art would have found it obvious to use a telemetry device with the pulse generator 60 because Schwartz teaches data registers-telemetry in/out logic 110 is coupled to a telemetry antennae 124 for receiving and transmitting programming and telemetry data to the external transceiver or programmer in a manner well known in the pacing art.

Claims 7-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz '507 in view of Collins '326.

Schwartz shows all of the claimed features except for overdrive pacing.

Collins teaches performing overdrive pacing, wherein a pacemaker decreases the natural interval by a predetermined amount or predetermined percentage and begins generating cardiac pacing pulse stimulations at the new rate. The new interval between paces is labelled "Escape Interval" in FIG. 13A and FIG. 13B. The antiarrhythmia pacemaker waits a predetermined cardio-

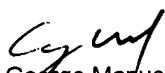
Art Unit: 3762

neural delay (CN Delay) amount, then begins stimulating the vagal cervical ganglion. If the pacemaker is programmed to generate multiple pulses within a burst, as shown in FIG. 13A, the predetermined parameters of Burst Duration and interpulse interval (IPI) determine the form of the burst. Multiple pulse bursts are preferred in the case of confirmed arrhythmias, and a vagal stimulation in the form of a single pulse or a short burst of pulses may not be an appropriate therapy in response to the detection of a high rate arrhythmia because repetitive stimulation of parasympathetic nerves, at a rate similar to the heart rate, tends to entrain S-A nodal pacemaker cells, so that the heart rate will take on the same frequency as that of vagal stimulation. Therefore, for high rate arrhythmias, single pulse or short burst neural stimulation could lead to heart rates which are inappropriately high during pacing.

One of ordinary skill in the art would have found it obvious to combining the teaching of Collins for programming the pulse generator 60 of Schwartz because the teaching applies to vagal stimulation in an implantable device for controlling arrhythmias.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George Manuel whose telephone number is (703) 308-2118.


George Manuel
Primary Examiner
Art Unit: 3762

7/8/04